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(Reaffirmed 2001)

SPECIFICATION FOR ANAESTHETIC APPARATUS, DRAWOVER PORTABLE TYPE

(First Revision)

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NEW DELHI 110002

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Indian Standard

SPECIFICATION FOR ANAESTHETIC APPARATUS, DRAWOVER PORTABLE TYPE

(First Revision)

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Indian Standard

SPECIFICATION FOR
ANAESTHETIC APPARATUS, DRAWOVER
PORTABLE TYPE

(First Revision)

0. FOREWORD

0.1 This Indian Standard (First Revision) was adopted by the Indian Standards Institution on 27 December 1985, after the draft finalized by the Anaesthetic Resuscitation and Allied Equipment Sectional Committee had been approved by the Consumer Products and Medical Instruments Division Council.

0.2 This standard is one of a series of Indian Standards dealing with anaesthetic equipment and medical breathing machines.

0.3 This standard contains 13.1 which calls for an agreement between the purchaser and the supplier which permits the purchaser to use his option for selection to suit his requirements.

0.4 This standard was first published in 1974. The first revision of this standard has been undertaken to incorporate additional constructional details, storage conditions and suitable sampling plan.

0.5 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard prescribes constructional and other requirements of portable type drawover anaesthetic apparatus.

***Rules for rounding off numerical values (*revised*).**

2. MATERIAL

2.1 The material used shall be as given in relevant clauses of this standard. Where possible, material shall be corrosion resisting. If this is not practicable and specially where corrosion products can adversely affect the performance of the apparatus, the components shall be electroplated or otherwise protected to give a corrosion-resisting, non-reacting surface.

3. CONSTRUCTION

3.1 The apparatus for vapourizing a liquid anaesthetic by air alone or a mixture of air and oxygen shall consist of the following:

a) Inflating bags of spring loaded concertina type or self-inflating type;

b) A vapourizing unit accurately calibrated and compensated for variation of ambient temperature and altitude;

c) A set of breathing attachment consisting of:

  1) Nonkinking type flexible corrugated breathing tube approximately 1 metre long (The material shall conform to the relevant requirements of IS : 5680-1969[*]),
  2) Expiratory valve conforming to IS : 8254 (Part 2)-1978[†],
  3) Pace mask conforming to IS : 6190-1971[‡];
  4) Catheter mount; and
  5) Other necessary attachments to complete the breathing circuit.

d) A nonkinking type flexible corrugated tubing connection between inflating bags and the vapourizer (approximately 30 cm long); and

e) An oxygen flowmeter or a fine adjustment valve conforming to general requirements of IS : 6513-1985[§] with a small oxygen cylinder provided with a pressure reducing device conforming IS : 8382-198311, shall be provided.

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[*] Specification for rubber tubing for medical use.

[†] Specification for valve non-rebreathing: Part 2 Ambu-hesse's pattern.

[‡] Specification for anaesthetic face mask.

[§] Specification for fine adjustment valve for use with oxygen cylinders for oxygen therapy (*first revision*).

[||] Specification for pressure regulators, pre-set type, used with medical gas cylinders.

3.2 Inflating Bags

3.2.1 A concertina type bags with suitable metal plates on top and bottom shall have an internal volume of approximately 2·5 litres. The self-inflating bags shall have an internal volume of approximately 2 litres.

3.2.2 An adaptor fitting for oxygen supplementation shall be provided at the inlet side of the assembly and also of vapourizing unit, for example, a Rama Rao type adaptor.

3.2.3 The rubber parts shall be made of good quality natural rubber and shall be capable of ageing in an air-oven for 168 h at 70 ± 1°C without showing appreciable stiffening, cracking or other changes in condition.

3.3 Vaporizing Unit

3.3.1 For a given setting of concentration of the anaesthetic mixture delivered at the patient end, the concentration shall remain accurate within the limits specified in 5.

3.3.2 The unit shall be designed to take care of variations in ambient conditions as specified in 5.

3.3.3 The unit shall be designed to take care of variations in respiratory conditions as specified in 7.

3.3.4 Resistance to breathing shall be not more than 1·5 cm of water at a constant flow rate of 40 litre/min.

3.3.5 There shall be no noticeable peak concentration when the control is moved from zero position.

3.3.6 Accidental jarring of the unit and of the liquid contained in it shall not significantly affect the concentration.

3.3.7 A visible indication shall be provided to keep a check on the anaesthetic liquid level.

3.3.8 The unit shall be robust and shall be capable of withstanding adverse climatic and environmental changes during transit and storage.

4. RANGE OF CALIBRATION

4.1 The calibration range, when designed for various anaesthetic agents, shall be as follows:

a) Ether	O-20 percent (*v/v*)
b) Fluothane	O-4 percent (v/v)
c) Furane	O-3 percent (*v/v*)
d) Trichloroethylene	O-3 percent (*v/v*)

5. CALIBRATION ACCURACY

5.1 Variation from the indicated figure shall be within ±10 percent of the indicated figure, for example, if the vapourizer is indicating X percent mixture then the upper limit would be ($X + \frac{10X}{100}$) percent, the lower limit being ($X - \frac{10X}{100}$) percent (see *also* Appendix A).

6. AMBIENT CONDITIONS

6.1 It shall be possible to operate the unit at ambient temperatures from 15 to 35°C, up to an altitude of 3 657 m.

7. STORAGE CONDITIONS

7.1 The unit when stored shall be capable of withstanding a temperature of —20° to 50°C without showing appreciable stiffening, softening, cracking or other change in condition.

8. RESPIRATORY CONDITIONS

8.1 The unit shall be designed to operate at the following conditions:

a) Respiratory rate	IO-30 per minute
b) Tidal volume	100-I 000 ml
c) Minute volume	4-15 litre

8.2 In addition to above, the unit shall perform satisfactorily with a continuous flow of 4 to 15 litre/min.

9. CONNECTIONS

9.1 Inport and outport connections, attachments adaptors, etc, shall conform to IS : 7409-I 985*.

10. MASS

10.1 The mass of the entire apparatus, complete with carrying case, excluding the mass of the cylinder shall be less than 16 kg.

11. MARKING

11.1 The apparatus shall be marked with the manufacturer’s name, initials or registered trade-mark and the country of origin.

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*Specification for breathing attachments for anaesthetic apparatus (*first revision*).

11.1.1 The apparatus may also be marked with the ISI Certification Mark.

NOTE — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act and the Rules and Regulations made thereunder. The IS1 Mark on -products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system of inspection, testing and quality control which is devised and supervised by ISI and operated by the producer. ISI marked products are also continuously checked by ISI for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

12. OPERATING MANUAL

12.1 Each apparatus shall be accompanied by an operating manual which shall contain the following information:

a) Instructions for use,

b) Routine maintenance and service,

c) Operation of the apparatus, and

d) Altitude.

13. PACKING

13.1 As agreed to between the purchaser and the supplier.

14. SCALE OF SAMPLING AND CRITERIA FOR CONFORMITY

14.1 Lot — In any consignment, all the portable type drawover anaesthetic apparatus produced from the same material under similar conditions shall constitute a lot.

14.2 Number of anaesthetic apparatus to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 1.

TABLE 1 SCALE OF SAMPLING

LOT SIZE	SAMPLE SIZE
up to 15	2
16 - 25	3
26 - 100	5
101 - 150	a
151 and above	13

14.2.1 These apparatus shall be selected from the lot at random and in order to ensure the randomness of selection, procedures given in IS : 4905-1968*, may be followed.

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*Methods for random sampling.

14.3 Number of tests and criteria for conformity of the apparatus selected at random in accordance with col 1 and 2 of Table 1 shall be tested for construction, inflating bags, vaporizing unit, calibration accuracy, respiratory conditions, connections and mass. The lot shall be considered as conforming to these requirements if none of the apparatus in the sample is found to be defective in any of these tests.

APPENDIX A

(Clause 5)

METHOD OF TESTING ACCURACY OF CALIBRATION OF THE APPARATUS

A-l. METHOD

A-1.0 A portable sine wave pump is desirable for this purpose but if not available manually operated inflating bags of not less than 600 ml displacement and fitted with unidirectional valves may be used for the purpose.

A-l.1 Throughout the mixture analysis checks, the pressure control on the machine (if fitted) is set to the on-demand position. In place of the normal facepiece and corrugated hose assembly, the inlet of the test bags is plugged directly into the outlet of the apparatus under test, The outlet of the test bags is in turn connected to a double ended rubber bag having a restricted outlet of such size as to prevent the bag from emptying between strokes of the bags.

A-l.2 The ‘bag is operated at a rate of approximately 20 strokes per minute, and the stroke volume maintained as nearly as possible at 600 ml. After at least 5 strokes of the bags thoroughly to flush the system, the contents of the rubber bag are sampled.

A-l.3 At least three analysis are to be made and this is to be repeated at three different mixture settings, for example, at 10 percent, 20 percent and 50 percent oxygen marks. The sample shall be tested in a refractometer. It shall satisfy the requirements given in 5.